ACCUTOME

JAN 29 2013

510(k) SUMMARY: A-Scan Plus Connect

Applicant:	Accutome, Inc. **Note:** Accutome Ultrasound, Inc. (listed as the manufacturer for the predicate device) is a wholly owned subsidiary of Accutome, Inc. and is located in the same facility. Accutome, Inc. is in the process of moving all device listings to the Accutome, Inc. name only.
Address:	3222 Phoenixville Pike Malvern, PA 19355
Contact Person:	Adam Pickholtz Manager QA/QC
Telephone:	(610) 889-0200 (610) 889-3233 Fax
Preparation Date: **Revision Date:**	October 26, 2012 December 5, 2012
Trade Name:	A-Scan Plus Connect
Common Name:	Biometer
Classification Name:	System, Imaging, Pulsed Echo, Ultrasonic (21 CFR 892.1560, Product Code: IYO) Diagnostic Ultrasound Transducer (21 CFR 892.1570, Product Code: ITX)
Legally Marketed Predicate Devices:	Accusonic A-Scan (K032956) *There have been no prior FDA submissions for the A-Scan Plus Connect.
Description of the Device:	The Accutome A-Scan Plus Connect device is designed as a biometer, which uses pulsed echo ultrasound to measure the

axial length, and the location of other structures of the eye. It utilizes an eye-contact probe to generate and receive the ultrasound pulses, and provides a one-dimensional display of returning pulse echoes, with positive peaks to indicate the location of ocular structures. The distance between peaks can be measured.

Indications for Use:

This instrument is used for measuring the axial length, anterior chamber depth and lens thickness of the eye. It also is used for calculating the optical power of the IOL to be implanted during cataract surgery.

Comparison of Technological Characteristics to the predicate device:

All of the critical functions of the A-scan Plus Connect are calculated in exactly the same manner as in the predicate device Accusonic A-Scan. The probe used with the A-Scan Plus Connect is exactly the same as the probe used on the Accusonic A-Scan. The software algorithms for clinically critical functions, i.e. to process ultrasound measurements and calculate intraocular lens parameters remain exactly the same as in the predicate device.

The new A-Scan Plus Connect model uses the personal computer as the main computing vehicle and display instead of the dedicated computer/display of the predicate device. The software modifications in the Connect model are those necessary to interface the processing, data storage, display, and printing capabilities of the personal computer.

The A-Scan Plus connect control unit is an interface between the ultrasonic probe and a personal computer. It consists of a microprocessor based printed circuit board, with USB connections, enclosed in a plastic case.

The energy source for the A-Scan Plus Connect is USB power from the personal computer instead of the AC to DC adapter used to power the predicate device.

The chemical composition of patient contact materials is identical to that of the predicate device.

Standards Testing:

EN 60601-1 Medical Electronic Equipment Part 1: General Requirements for Safety
Both this device and the predicate were tested to, and found to be compliant with EN 60601-1.

EN 60601-1-2 Collateral Standard: Electromagnetic Compatibility – Requirements and Tests

Both this device and the predicate were tested to, and found to be compliant with EN 60601-1-2.

IEC 60601-2-37 - Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment
Acertara Acoustic Laboratories evaluated the device in May and June 2012 in accordance with IEC 60601-2-37:2007 and Section 1.6.1 of the September 2008 FDA Guidance Document. Sonora Medical Systems (now Acertara Acoustic Laboratories) evaluated the predicate device in March 2002 in accordance with Section 4.6.1 of the September 1997 FDA Guidance Document.

EN/ISO 10993 - Biological Evaluation of Medical Devices

Compliance per Toxikon Test Reports 03-1518-G1 dated 03 April 2003, 03-1518-G2 dated 16 May 2003, and 03-1518-G3 dated 18 April 2003. The same probe is used with this device as with the predicate device; the materials have not changed.

Verification Testing:

Physical Accuracy Test
This test compares the distance measured ultrasonically by the A-Scan Plus Connect and the physical distance measured by a mechanical dial indicator. The test results for both the A-Scan Plus Connect model and the predicate device were well within the 0.1mm acceptance criteria.

Results:
Both the A-scan Plus Connect model and the predicate device were well within the 0.1mm acceptance criteria.

Data Comparison Test: Accusonic A-Scan (predicate) vs. A-Scan Plus Connect

The objective of this test is to compare critical parameter results between the two devices under conditions of the same input test fixture and values.

Results:
All of the data met the established acceptance criteria:
-Ultrasound measurements for all eye types shall be within 0.05mm
-IOL calculation results for all formulas shall be within one decimal place

Validation Testing:

Internal Validation Tests

A test plan was developed to evaluate proper operation and usability for all device modes/options. The plan consisted of 83(as of 12/5/12) specific evaluations of characteristics of the device, most of which required multiple actions or observations on the part of the user.

Results:

All operations and features were fully functional. There were no errors or deficiencies in the patient information. The usability was judged to be superior to the predicate device.

External Validation Tests

A checklist was developed which requests quantified critique regarding the safety, functionality and usability of the device via 11 specific questions. A Rating Scale from 1 to 5 was used with:
5 = best, very user friendly, no problems; and 1 = not acceptable, very unfriendly, significant problem that must be corrected.

Results:

The device was evaluated on 29 different patients at 3 different locations by 3 different experienced technicians/ophthalmologists. One of the users had detailed experience with the predicate device and two with a competitive biometer.

Safety was ranked 5 by every user. The average rating for the 9 specific attributes enumerated was 4.8. The "Overall Rating" of the device was 5 by all users. There were no ratings of 1 or 2 in any of the tests.

Validation Tests Summary

The internal and external validation tests demonstrate that there are no known safety issues with the A-Scan Plus Connect device.
The tests further demonstrate that there are no significant functionality issues and that the usability of the device is superior to that of the predicate device.

Conclusion:

The positive results of the testing above, along with the risk analysis performed, demonstrate that the A-Scan Plus Connect is at least as safe and as effective, and has improved usability, when compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

February 13, 2013

Accutome, Inc
c/o Adam Pickholtz
Regulatory Manager
3222 Phoenixville Pike
MALVERN PA 19355

Re: K123349
Trade/Device Name: A-Scan Plus Connect
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO and ITX
Dated: January 17, 2013
Received: January 22, 2013

Dear Mr. Pickholtz:

This letter corrects our substantially equivalent letter of January 29, 2013.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducer intended for use with the A-Scan Plus Connect, as described in your premarket notification:

10 mhz

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Robert Ochs at (301) 796-6661.

Sincerely yours,

Sean M. Boyd -S for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123349

Device Name: A-scan Plus Connect

Indications for Use:

This instrument is used for measuring the axial length, anterior chamber depth and lens thickness of the eye. It also is used for calculating the optical power of the IOL to be implanted during cataract surgery.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Sean M. Boyd -S

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k)_____K123349_____

Tab 2- IFU Tables

System: Accutome A-Scan Plus Connect

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	A	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic	P						
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel							
Vessel	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Examples of other modes of operation may include: B-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

Sean M. Boyd -S
(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

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Transducer: 10 mhz

Clinical Application		Mode of Operation						
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**A**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify)**	**Other* (Specify)**
Ophthalmic	Ophthalmic	P						
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal **(Conventional)**							
	Musculo-skeletal **(Superficial)**							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel							
Vessel	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Examples of other modes of operation may include: B-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

Sean M. Boyd -S

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

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